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EXAMINER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

1. The Examiner acknowledges the copies of the copies of the Transmittal Sheet and Response to Restriction Requirement filed via the mail on February 26, 2008 and a copy of the Return Receipt postcard date-stamped by the US Patent and Trademark Office on February 28, 2008. The response was entered August 28, 2008.

### ***Election/Restrictions***

2. Claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 26, 2008 and resubmitted on August 28, 2008.
3. Claims 1-13 are currently pending.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-10 and 12-13, 15-19, and 21 of U.S. Patent No. 6,656,195 in view of Aznoian et al. U.S. Patent No. 5,908,381. Although the conflicting claims are not identical, they are not patentably distinct from each other. The patent and the instant application are claiming common subject matter including: a flexible inner tube rotatably disposed within an outer tube; the inner tube being of solid construction with a helical cut in a first direction and a spiral wrap disposed over the helical cut in a second opposite direction; a cutting configuration and a cutting port disposed on the inner and outer tubes respectively; and an aspiration passage. Although, a plurality of bends is not claimed in the patent, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a plurality of bends to enable the surgeon to better manipulate the instrument (see Aznoian). Furthermore, the specifics of the stepped pattern are considered obvious design choices, as applicant failed to specify that these were critical in any way, failed to state how these limitations solved any particular problem, or were for any particular purpose, and the Examiner contends that any difference in the specifications claimed by the patent with respect to the above limitations would have performed equally as well as the specific claim limitations of the instant application.

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6. Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6-16, and 20-22 of U.S. Patent No. 6,533,749 in view of Aznoian et al. U.S. Patent No. 5,908,381. Although the conflicting claims are not identical, they are not patentably distinct from each other. The patent and the instant application are claiming common subject matter including: a flexible inner tube rotatably disposed within an outer tube; the inner tube being of solid construction with a helical cut in a first direction and a spiral wrap disposed over the helical cut in a second opposite direction; a cutting configuration and a cutting port disposed on the inner and outer tubes respectively; and an aspiration passage. Although, a plurality of bends is not claimed in the patent, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a plurality of bends to enable the surgeon to better manipulate the instrument (see Aznoian).

### ***Claim Rejections - 35 USC § 102***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 6, 7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al. (US 2002/0038129). Peters et al. disclose an angled tissue cutting instrument (Figs 1-9) comprising outer and inner tubular members (12 and 14). The inner tubular member a continuous helical cut (39) formed in a step pattern at an angle in a first direction to impart flexibility (¶0033-0034) and a cutting configuration (70) at the distal end. A cutting port (28) disposed on the outer tubular member exposes the

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cutting configuration (¶0044). A single layer of spiral wrap (68) is disposed over the helical cut at the same angle in an opposite direction and ends of the spiral wrap are secured to the inner tubular member (¶0039). An aspiration passage extends through the inner tube (¶0042) and an aspiration port (88) is disposed at the distal end of the inner tube. The stepped pattern of the helical cut comprises a transverse cut segment (Fig 12 – from corners 355 to 355) and a longitudinal cut segment (from corners 355 to 359) where the transverse segment extends at a 20 degree angle relative to a plane perpendicular to the longitudinal axis (¶0053).

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (US 2002/0038129), as applied to claim 1 above, in view of Aznoian et al. (US 5,908,381). Peters et al. disclose the invention substantially as claimed including a bend (22) in the outer tubular member. Furthermore, Peters et al. disclose the dimensions, location, and direction of the bend are dependent upon the procedure to be performed and the location of the operative site to be accessed (¶0032). However, Peters et al. do not disclose the instrument specifically comprises a plurality of bends. Aznoian et al. discloses disclose a similar endoscopic instrument with a plurality of bends that extend in different directions at different angles (Fig 1, elements 50 and 52), where the proximal bend (52) is bent at a first angle of 45 degrees from the proximal

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length portion and the distal bend (50) is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion (col 6, lines 39-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Peters et al. such that the outer tubular member comprised a second bend that extends in a different direction at a different angle, such that the proximal bend is bent at a first angle of 45 degrees from the proximal length portion and the distal bend is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion. Thus, the instrument would be easier for the surgeon to manipulate around tortuous paths. Furthermore, it would be obvious to modify the device of Peters et al. to include a plurality of helical cuts and single layers of spiral wrap along the additional length portions created with the additional bends because Peters et al. teaches the helical cuts and the spiral wrap enhance the function of the cutting instrument and impart flexibility at the bends (¶0012).

11. Claims 8, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (US 2002/0038129), as applied to claims 7, 9, 14, and 16 above. Peters et al. disclose the invention substantially as claimed as shown above. However, Peters et al. do not disclose the dimensions of the rotational intervals or the length of the transverse and longitudinal cut segments. Applicant has not disclosed that having the steps repeat at rotational intervals of 100 degrees or having the length of the transverse segment greater than the length of the longitudinal segment solves any

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stated problem or is for any particular purpose. Moreover, it appears the stepped pattern of Peters et al., or applicant's invention, would perform equally well with the stepped pattern repeating at any rotational interval and comprising any ratio of cut segment lengths. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Peters et al. such that the stepped pattern repeated at rotational intervals of 100 degrees about the central longitudinal axis and comprised a longer transverse cut segment than longitudinal cut segment because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Peters et al.

### ***Response to Arguments***

12. Applicant's arguments filed on February 26, 2008 and resubmitted on August 28, 2008 have been fully considered but they are not persuasive.

13. Regarding the rejection of claims 1-13 on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1, 6-10, 12-13, 15-19, and 21 of U.S. Patent No. 6,656,195 to Peters et al. in view of U.S. Patent No. 5,908,381 to Aznoian et al., Applicant argues the Peters patent and the instant application do not claim common subject matter. Applicant argues the claims of the Peters patent require a helical cut to be formed in the inner tube in a pattern defining interlocking tenons and mortises between adjacent tube segments, and interlocking tenons and mortises form no part of the instant claimed invention. The Examiner respectfully traverses the Applicant's remarks. There is a significant amount of common subject matter claimed



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including: a flexible inner tube rotatably disposed within an outer tube; the inner tube being of solid construction with a helical cut in a first direction and a spiral wrap disposed over the helical cut in a second opposite direction; a cutting configuration and a cutting port disposed on the inner and outer tubes respectively; and an aspiration passage. The interlocking tenons and mortises may be interpreted as a “stepped pattern”. The Examiner notes the “stepped pattern” is defined in the claims as comprising:

“repeating steps each made up of a transverse cut segment extending transverse to the length of said inner tube in a first direction about said inner tube and at an angle to a plane perpendicular to said central longitudinal axis, and a longitudinal cut segment extending from said transverse cut segment along the length of said inner tube” (claim 9, lines 17-21).

Thus, the Peters patent discloses a stepped pattern as shown in Figure 12, where the step comprises a transverse cut segment (from corners 355 to 355) and a longitudinal cut segment (from corners 355 to 359). Furthermore, it would be obvious design choice to place the angle specifically at 20 degrees and repeat at rotational intervals of about 100 degrees about the longitudinal axis. Applicant argues it would not have been an obvious design choice to have a stepped pattern. The Examiner respectfully traverses the Applicant's remarks because the stepped pattern is disclosed by the Peters patent; the specific dimensions though would have been an obvious design choice. Applicant has not provided sufficient arguments to clearly point out the novelty of the specific dimensions discussed above.

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14. In response to applicant's argument that there is no suggestion to combine the references of Peters et al. (US 6,656,195) and Aznoian et al. (US 5,908,381), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Aznoian et al. disclose a similar instrument with a plurality of bends that extend in different directions at different angles (Fig 1, elements 50 and 52), where the proximal bend (52) is bent at a first angle of 45 degrees from the proximal length portion and the distal bend (50) is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion (col 6, lines 39-55). Aznoian et al. teach bends in the distal region of surgical instruments are desired to permit the operator to accurately position the instrument and depending on the application a single bend may be advantageous or a plurality of bends may be advantageous (col 7, lines 7-18). The Aznoian et al. reference is thus used to teach the general concept of including a plurality of bends in the distal region of a device. Thus, in view of Aznoian et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Peters et al. to include a second bend in the distal region of the device.

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15. Regarding the rejection of claims 1-8 on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1, 2, 6-16, and 20-22 of U.S. Patent No. 6,533,749 to Mitusina et al. in view of U.S. Patent No. 5,908,381 to Aznoian et al., Applicant argues the Peters patent and the instant application do not claim common subject matter. Applicant argues Mitusina does not claim forming a helical cut in a "stepped pattern". The Examiner respectfully traverses the Applicant's remarks and notes the claimed "stepped pattern" is defined in claims 1-8 as repeating at rotational intervals of about 100 degrees and comprising repeating interconnected steps. The pattern formed by the helical cut as shown in Figure 4 of Mitusina et al. may thus be interpreted as a "stepped pattern".

16. Applicant's arguments, see remarks, filed on February 26, 2008 and resubmitted on August 28, 2008, with respect to the rejection of claims 9-13 on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1, 2, 6-16, and 20-22 of U.S. Patent No. 6,533,749 to Mitusina et al. in view of U.S. Patent No. 5,908,381 to Aznoian et al., have been fully considered and are persuasive. Mitusina does not recite the claimed stepped pattern as defined in lines 17-21 of claim 9. The rejection of claims 9-13 over Mitusina has been withdrawn.

17. Regarding the rejection of claims 1-13 as being anticipated by the Peters et al. publication (2002/0038129), Applicant argues the Peters publication fails to disclose a helical cut formed in the inner tube in a stepped pattern. The Examiner respectfully

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traverses the Applicant's remarks. As stated above, the Examiner notes the "stepped pattern" is defined in the claims as comprising:

"repeating steps each made up of a transverse cut segment extending transverse to the length of said inner tube in a first direction about said inner tube and at an angle to a plane perpendicular to said central longitudinal axis, and a longitudinal cut segment extending from said transverse cut segment along the length of said inner tube" (claim 9, lines 17-21).

Thus, the Peters publication discloses a stepped pattern as shown in Figure 12, where the step comprises a transverse cut segment (from corners 355 to 355) and a longitudinal cut segment (from corners 355 to 359).

Applicant additionally argues the Peters publication does not recognize the limitation that there be no more than a single layer of spiral wrap disposed over the helical cut formed in the inner tube. The Examiner respectfully traverses the Applicant's remarks. As shown in Figure 2, only a single layer of spiral wrap (68) is disposed over the helical cut at the same angle in an opposite direction and ends of the spiral wrap are secured to the inner tubular member (§0039). First (192) and second (168) spiral wrap layers are only shown in the alternative embodiment of Figure 10 (§0046).

### ***Conclusion***

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

Katherine Dowe  
December 30, 2008

/K. M. D./  
Examiner, Art Unit 3734